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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,520

04/06/2004

Nicholas Francis Fell JR.

ARL 04-06

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21364 7590 02/08/2007  
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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/828,520	Applicant(s) FELL ET AL.	
	Examiner Nathan A. Bowers	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 25, 26, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Vanderberg (US 6599715).

With respect to claims 25 and 26, Vanderberg discloses a bacterial endospore detection system comprising an optical detection device that further includes a flow cell (Figure 2:22).

The optical detection device additionally comprises a light source (Figure 2:26) and a photodetector (Figure 2:28). A flowpath (Figure 2:14) fluidly connects a sampler to the flow cell. This is described in column 2, lines 31-55 and column 4, line 56 to column 5, line 5.

Column 4, lines 14-31 specifically describe an embodiment in which the light source is used to emit light at a wavelength of 276 nanometers. Vanderberg additionally discloses a marker chemical complexing agent reservoir in which terbium nitrate is stored. This reservoir is fluidly connected to the flow cell so that terbium ions are allowed to complex with dipicolinic acid produced by spores in a sample solution.

With respect to claims 28 and 29, Vanderberg discloses the apparatus in claim 25 wherein additional fluid reservoirs are provided to add chemicals during the detection process.

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This is clearly illustrated in Figure 2. These supplementary reservoirs are fully capable of holding any biochemical agents, such as enhancement and release agents.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderberg (US 6599715) as applied to claim 25, and further in view of Floriano (US 20060079000).

Vanderberg discloses the apparatus set forth in claim 25 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly indicate that the optical detection device includes an optical analysis device.

Floriano discloses a bacterial endospore detection system comprising an optical detection device (Figure 3:250) that includes a flow cell. Flow paths are provided for moving samples to and from the optical detection device. A sampler in the form of a sample input is additionally provided. This is apparent from Figure 3 and paragraphs [0058], [0059] and [0079]-[0081]. Paragraphs [0059] and [0069] state that the detection device includes a computer system capable of analyzing data obtained from the detector.

Vanderberg and Floriano are analogous art because they are from the same field of endeavor regarding endospore detection.

At the time of the invention, it would have been obvious to incorporate an optical analysis device in the optical detection device disclosed by Vanderberg. Optical analysis devices are considered to be notoriously well known in the art. In paragraph [0069], Floriano indicates that computer systems are beneficial when utilized in data processing because they are capable of thoroughly analyzing information quickly and efficiently.

3) Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderberg (US 6599715) as applied to claim 25, and further in view of Muller (US 5804384).

Vanderberg discloses the apparatus set forth in claim 25 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly indicate that the flow path includes a mixing zone.

Muller discloses an analyte detection system that comprises an optical detection device that includes a flow cell (Figure 1:18). A laser (Figure 2:54) and a photodetector (Figure 2:56) are provided for determining the presence of a target molecule in a sample. A syringe (Figure 1:22) works as a sampler since it is used to deliver analytes to the detection device via a flowpath (Figure 1:28). The flowpath includes a heated mixing zone (Figure 1:20). A heater (Figure 1:36) produces a temperature in the zone that facilitates mixing and binding between analytes and complexing agents. This is disclosed in column 9, lines 5-25.

Vanderberg and Muller are analogous art because they are from the same field of endeavor regarding endospore detection systems.

At the time of the invention, it would have been obvious to provide a heated mixing zone in the apparatus of Vanderberg upstream from the detection area. This would have been advantageous because it would have better enabled reaction between marker chemical complexing agents and bacterial endospore compounds, thus increasing the sensitivity of the detection. The incorporation of a mixing zone in the apparatus of Vanderberg would have required little structural modification, especially since the disclosed germination chamber (12) of Vanderberg is fully capable of accommodating mixing. At the time of the invention, it would have also been obvious to utilize a laser in the optical detection system of Vanderberg. As evidenced by Muller, lasers are well known in the art.

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4) Claims 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderberg (US 6599715) as applied to claim 25, and further in view of Applicant's admitted prior art.

Vanderberg discloses the apparatus set forth in claim 25 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly disclose the use of a phosphate interference suppression agent as a chemical enhancement agent.

Applicant discloses on page 4 of the specification that it is known in the art that phosphate compounds in buffer solutions have an inhibiting effect on luminescent detection processes. Applicant also discloses that it is known that the addition of aluminum ions is an effective way to remove phosphate from a sample solution.

At the time of the invention, it would have been obvious to utilize a phosphate interference suppression agent in the system disclosed by Vanderberg in order to increase detection sensitivity. In Applicant's specification, it is admitted that the inhibiting effect of buffers on detection is known in the art, as well as the use of phosphate interference suppression agents to rectify the problem. Specifically, Applicant teaches that the use of aluminum ions has been reported in the past.

5) Claims 28, 29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderberg (US 6599715) as applied to claim 25, and further in view of Pellegrino "Enhanced spore detection using dipicolinate extraction techniques."

Vanderberg discloses the apparatus set forth in claim 25 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly disclose the use of a release agent.

Pellegrino discloses a bacterial endospore detection system in which dodecylamine (dda) is added to the sample solution in order to increase detection sensitivity. This is disclosed in the abstract and throughout the reference. Pellegrino additionally indicates in the introduction that aluminum salts are added in order to suppress the adverse effects of phosphates during detection.

Vanderberg and Pellegrino are analogous art because they are from the same field of endeavor regarding endospore detection.

At the time of the invention, it would have been obvious to add the enhancement agents and release agents disclosed by Pellegrino to the system of Vanderberg in order to enhance the sensitivity of the detection operation. Pellegrino states that the use of dodecylamine results in a two-order of magnitude improvement in endospore detection. As described in the previous rejection, the use of enhancement agents also work to ensure that the system is able to accurately determine endospore levels in a sample.

### *Response to Arguments*

Applicant's arguments filed 17 November 2006 with respect to the 35 U.S.C. 102 rejection involving Floriano have been fully considered and are persuasive. Floriano does not disclose a narrow bandwidth light at a wavelength between 260 and 280 nm. These rejections have been withdrawn.

Applicant's arguments filed 17 November 2006 with respect to the 35 U.S.C. 102 rejection involving Muller have been fully considered and are persuasive. Muller does not



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disclose a narrow bandwidth light at a wavelength between 260 and 280 nm. These rejections have been withdrawn.

Applicant's arguments filed 17 November 2006 regarding the 35 U.S.C. 102 rejection involving Vanderberg have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) An affidavit was filed showing that the currently claimed device yields a 200 fold improvement in results shown in the Vanderberg patent. This result is unexpected for the differences in the structure of the Vanderberg batch process and the instant invention.*

In response to Applicant's arguments, please consider the following comments.

There are no structural differences between the claimed invention represented by independent claim 25 and the device of Vanderberg. As set forth in the rejections above, Vanderberg discloses (1) an optical detection device, (2) a narrow band width light emitting device, (3) an optical flow cell, (4) a flow path, (5) a sampler, (6) and a marker chemical complexing agent reservoir. It is appreciated that Applicant's invention is capable of determining endospore concentration in a much more effective and sensitive manner. However, the *structures* that are responsible for these improvements must be presented in the claims as *structural* limitations.

Regardless, Applicant's declaration is defective because it does not clearly affirm that the stated superior results described in the declaration were, in fact, produced by the claimed invention. Applicant's statement on page 1 "data was collected on the system illustrated below *that operates in the same manner* as the currently claimed system" does not plainly indicate that

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the system described in the declaration *is* the same as the currently claimed system. The term “operates in the same manner” suggests that the unexpected results might have been obtained by a system that uses a similar method, but is physically different from the claimed system. Accordingly, the declaration is not commensurate in scope with the claimed invention.

Additionally, the Vanderberg reference is made under 35 U.S.C. 102. MPEP 2131.04 states that evidence of secondary considerations such as unexpected results is irrelevant to 35 U.S.C. 102 rejections, and thus cannot overcome a rejection so based.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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